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09/265,710 03/09/99 BANDMAN

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EXAMINER

HM12/0816

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ART UNIT

PAPER NUMBER

1646

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/265,710

Applicant(s)

Bandman et al.

Examiner

John Ulm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 18, 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 12, 21, and 42-57 is/are pending in the application.
- 4a) Of the above, claim(s) 46, 47, and 52-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 12, 21, 42-45, and 48-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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1) Claims 1, 2, 12, 21 and 42 to 57 are pending in the instant application. Claims 2 and 21 have been amended, claims 13 to 18 and 23 to 41 have been canceled and claims 42 to 57 have been added as requested by Applicant in Paper Number 16, filed 18 June of 2001.

2) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) The request filed on 18 June of 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/265,710 is acceptable and a CPA has been established. An action on the CPA follows.

5) Newly submitted claims 46, 47 and 52 to 57 are directed to multiple inventions that are independent or distinct from the invention originally claimed for the following reasons:

The invention of claim 46 and the elected invention are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the protein, as claimed, can be made synthetically or isolated from a natural source, each of which is a process that is materially different from the recombinant process of claim 46..

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Claim 47 is drawn to an antibody, which is a materially different compound than the putative receptor protein of the elected invention. Distinctness is shown by the fact that each of these compounds can be made and used without the other and because they lack a common utility which is based upon a shared structural feature lacking from the prior art and disclosed as the basis for that common utility.

Claims 52 to 55 are drawn to an analytical process of using the claimed polypeptide wherein the claimed process is materially different from the antibody production method of claims 56 and 57, which also employs the claimed polypeptide. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). Because the claimed polypeptide can be used in the two materially different processes claimed, it is distinct therefrom for restriction purposes.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 46, 47 and 52 to 57 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

6) Claim 21 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or

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rewrite the claim(s) in independent form. A properly dependant claim can not conceivably be infringed without infringing any of the claims from which it depends.

7) Claims 1, 2, 12, 21, 42 to 45 and 48 to 51 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, substantial and specific asserted utility or a well established utility for those reasons of record as applied to claims 1, 2, 12 and 21 in section 4 of Paper Number 7. Applicant argues that the claimed polypeptides are useful as tools for toxicology testing, drug discovery, and the diagnosis of disease and that these uses are "well-established" and "specific". It is noted that toxicology testing and drug discovery are not specifically recited in the specification as originally filed. Each of the alleged uses in toxicology testing, drug discovery, and the diagnosis of disease will be addressed individually, because the facts and issues directed to each use are distinct and separable.

First, Applicant argues that toxicology testing is a well-established utility and concludes that any isolated polynucleotide encoding a naturally occurring polypeptide, including those polypeptides encompassed by the instant claims, could be used in this manner and that the claimed invention possesses specific and substantial utility in this capacity. However, for a utility to be "well-established" it must be specific, substantial and credible. In this case, as conceded by Applicant, all nucleic acids encoding naturally occurring polypeptides and the polypeptides encoded thereby are in some combination useful in toxicology testing. It is noted that the particulars of toxicology testing with SEQ ID NO:1 are not disclosed in the instant specification. Neither the toxic substances nor the susceptible organ systems are identified.

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virtually every member of a general class of materials, such as any collection of proteins or DNA. Even if the expression of Applicant's individual polypeptide is affected by a test compound in an array for drug screening, the specification does not disclose any specific and substantial interpretation for the result, and none is known in the art. Given this consideration, the individually claimed "isolated" polypeptide has no "well-established" use. The artisan is required to perform substantial further experimentation on the claimed material itself in order to determine to what "practical use" any expression information regarding this "isolated" polypeptide could be put.

The employment of a protein of the instant invention, or a nucleic acid encoding that protein, in toxicology testing is not a substantial and specific utility. As conceded by Applicant, all human proteins can be employed in such a process irrespective of their normal function. Such utilities are analogous to the assertion that a particular protein can be employed as a molecular weight marker, which is neither a specific or substantial utility.

One could just as readily argue that any purified compound having a known structure, such as the steroid compound which was the subject of the *Brenner v. Manson* decision cited above, could be employed as an analytical standard in such processes as nuclear magnetic resonance (NMR), infrared spectroscopy (IR), and mass spectroscopy as well as in polyacrylamide gel electrophoresis (PAGE), high performance liquid chromatography (HPLC) and gas chromatography. None of these important processes could be practiced without either calibration standards having known molecular structures or, at least, a range of molecular

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weight markers having known molecular weights. One could further extrapolate upon this premise by asserting that any item having a fixed measurable parameter can be employed to calibrate any machine or process which measures that parameter. For example, any item having a constant mass within an acceptable range can be employed to calibrate a produce scale in a grocery store. The calibration of produce scales is certainly an important function since most states require produce scales to be calibrated and certified. Therefore, to accept Applicant's arguments that any protein of human origin is useful in a toxicology test would be comparable to conceding that any object of fixed mass has *prima facie* utility as a weight standard, irrespective of any other properties possessed by that object. It was just such applications that the court appeared to be referring to when it expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation (*Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966)). Because the steroid compound which was the subject of that decision had a known structure and molecular weight it could have readily been employed as a molecular standard at that time. Further, because that compound was a hydrocarbon it certainly could have been employed in the well known process of combustion for purposes of lighting and/ or the generation of heat. The generation of heat by combustion of hydrocarbons certainly was and remains an important process. Irrespective of such obvious utilities, the court still held that the compound produced by the process at issue in *Brenner v. Manson* did not have a specific and substantial utility.

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To grant Applicant a patent encompassing an isolated naturally occurring human protein of as yet undetermined biological significance based upon Applicant's assertion that any human protein is useful in toxicology testing would be to grant Applicant a monopoly "the metes and bounds" of which "are not capable of precise delineation". That monopoly "may engross a vast, unknown, and perhaps unknowable area" and "confer power to block off whole areas of scientific development, without compensating benefit to the public" *Brenner v. Manson, Ibid*). To grant Applicant a patent on the claimed polypeptide based solely upon an assertion that it can be employed in toxicology testing is clearly prohibited by this judicial precedent since the compensation to the public is not commensurate with the monopoly granted and would be no different than granting a patent on the process disputed in *Brenner v. Manson* on the premise that the steroid produced thereby was useful as an analytical standard or as a fuel source..

Applicant's arguments that the "REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS" "Misstate the Law" will not be answered by the examiner. The contents of 35 U.S.C., 37 C.F.R., judicial decisions, and guidelines established by the USPTO are not subject to examiner review and will not be questioned or defended by the examiner. These are decisions made by legally empowered government entities to which the examiner is subordinate and those decisions will be followed without question by the examining corps.

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8) Claims 1, 2, 12, 21, 42 to 45 and 48 to 51 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

9) Claims 1, 2, 12, 21, 42, 44, 45, 48, 50 and 51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for those reasons of record in section 6 of Paper Number 7. Applicant's grounds for traversal of this rejection completely ignores the judicial precedent upon which the rejection is based. That traversal is in direct conflict with the controlling judicial precedent cited in the original rejection and, therefore, clearly unpersuasive.

10) Applicant's arguments filed 23 April of 2001 and 18 June of 2001 have been fully considered but they are not persuasive for those reasons given above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOHN ULM
PRIMARY EXAMINER
GROUP 1200



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